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K133217

SECTION 5.

510(k) SUMMARY

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(per 21 CFR §807.92)**

CIRRUS photo

GENERAL INFORMATION

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Classification Name: Tomography, Optical coherence
Camera, Ophthalmic, AC-powered

Product Code and Class: OBO – Class II
HKI – Class II

Classification Number: 886.1570
886.1120

Trade/Proprietary name: CIRRUS photo Models 600 and 800

PREDICATE DEVICES

Company: Carl Zeiss Meditec AG
Device: CIRRUS photo (K112184)

Company: Carl Zeiss Meditec, Inc.
Device: Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular,
Optic Nerve Head and Ganglion Cell Normative Databases
(K111157)

INDICATIONS FOR USE

The CIRRUS photo is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera which is suitable for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions.

These photographs support the diagnosis and subsequent observation of eye diseases which can be visually monitored and photographically documented. The CIRRUS photo is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures and measurement of central corneal thickness.

It also includes a Retinal Nerve Fiber Layer (RNFL), Optic Nerve Head (ONH), and Macular Normative Database which are quantitative tools for the comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

DEVICE DESCRIPTION

The CIRRUS photo is a computerized optical instrument that combines the diagnostic and imaging capabilities of the Carl Zeiss Meditec VISUCAM PRO NM Digital Camera and the Carl Zeiss Meditec Cirrus HD-OCT Optical Coherence Tomographer Model 4000. The CIRRUS photo was developed to provide both subjective and objective imaging, and to optimize space by combining fundus photography and spectral domain optical coherence tomography, allowing the anterior or posterior segments of the eye to be viewed and photographically documented with the pupil in a non-mydriatic or mydriatic state, within the same instrument. To optimize the workflow, the system applies the same optical beam delivery system for imaging and scanning.

The CIRRUS photo consists of a Fundus Camera Main Unit and a spectral domain optical coherence tomographer (SD-OCT) Module, both of which are installed on a single instrument table. The CIRRUS photo is operated via computer mouse, keyboard and joystick as part of the base of the main unit and an external monitor is mounted on top of the instrument table.

The CIRRUS photo is offered in two models, Model 600 and Model 800. Fundus auto fluorescence is available on both the Model 600 and 800; the Model 800 also offers fluorescein angiography and indocyanine green angiography (ICGA).

CIRRUS photo data can be analyzed using the same Cirrus HD-OCT algorithms and normative database cleared under K111157 (Cirrus HD-OCT software version 6.0), including

Advanced Retinal Pigment Epithelium (RPE) Analysis, Guided Progression Analysis (GPA) for Optic Nerve Head (ONH) parameters, and Ganglion Cell Analysis, and the Ganglion Cell Normative Database. As these algorithms and database reside separately on the Cirrus HD-OCT version 6.0 software, the analyses of the CIRRUS photo data are carried out using an external Cirrus Review station.

New Features

Measurement of Central Corneal Thickness

In addition to imaging anterior structures, the CIRRUS photo has the capability to measure central corneal thickness.

Advanced Retinal Pigment Epithelium (RPE) Analysis

The Advanced RPE Analysis allows the user to examine the status of the RPE in greater detail than the Macular Thickness Analysis using two Cirrus algorithms: one to identify and measure areas of sub-RPE illumination where the OCT is able to penetrate through to the choroid, indicating that the RPE is atrophic (often associated with geographic atrophy), and one to identify and measure elevations in the RPE (often associated with drusen).

Guided Progression Analysis (GPA) for Optic Nerve Head Parameters

GPA compares measurements from the Optic Disc cube 200 x 200 scan over time and determines if change over time has occurred that exceeds the test-retest variability. The analysis includes a chronological display of RNFL thickness maps, RNFL change maps, cup and disc boundaries, and thickness graphs representing rate of change for average thickness parameters and average cup-to-disc ratio as well as RNFL thickness profiles comparing the current exam to the baseline exams.

Ganglion Cell Analysis (GCA)

The Ganglion Cell Analysis (GCA) measures the thickness of the sum of the ganglion cell layer and inner plexiform layer (GCL + IPL) using data from the Macular 200 x 200 or Macular 512 x 128 cube scan patterns.

Ganglion Cell Normative Database

The CIRRUS Photo Retinal Nerve Fiber Layer (RNFL), Optic Nerve Head (ONH), and Macular Normative Databases were cleared under K112184.

The Cirrus Ganglion Cell normative database [for the Cirrus HD-OCT] was derived from an additional analysis of the macula normative database. To establish reference values, the scans acquired as part of the Cirrus HD-OCT Macular Thickness normative database were analyzed using a segmentation algorithm that identifies the thickness of the combined ganglion cell plus inner plexiform layers.

The database parameters are the same as those used in the original macula normative database. The Ganglion Cell database utilized the same 282 subjects, aged 19-84 years that were deemed representative of a normal population. The data was collected from seven sites. The normative database is age-corrected and has a gender distribution of 133 males, 149

females. Ethnicity breakdown of the normative database is as follows: 43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 6% mixed ethnicity.

SUBSTANTIAL EQUIVALENCE

It is the opinion of Carl Zeiss Meditec AG that the CIRRUS photo is substantially equivalent to the CIRRUS photo (K112184) and to the Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases (K111157). The indications for use for the CIRRUS photo is similar to the indications for the predicate devices cited in this application. A technological comparison and clinical testing demonstrate that the CIRRUS photo is functionally equivalent to the predicate devices.

Evaluation performed on the CIRRUS photo supports the expanded indications for use statement and demonstrates that the device is substantially equivalent to the predicate devices and does not raise new questions regarding safety and effectiveness.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The CIRRUS photo has very similar indications for use and operating characteristics as the predicate devices. The fundus camera unit of the proposed CIRRUS photo is exactly the same as the predicate CIRRUS photo (K112184) thus it utilizes the same imaging properties and technology as the cleared CIRRUS photo to record morphologic images of the human retina under mydriatic and non-mydriatic conditions, respectively. The SD-OCT Module is the same optical coherence tomography system as in the cleared CIRRUS photo instrument (K112184) and the Cirrus HD-OCT Optical Coherence Tomographer, Model 4000 (K111157).

The CIRRUS photo is therefore substantially equivalent to the predicate devices, i.e., the Carl Zeiss CIRRUS photo (K112184) and the Carl Zeiss Meditec Cirrus HD-OCT, Model 4000 (K111157).

BRIEF SUMMARY OF NON CLINICAL AND CLINICAL TESTS AND RESULTS

The CIRRUS photo has been designed and tested to the applicable standards for electrical and optical safety and verified to established specifications. In addition, clinical testing was conducted.

CLINICAL TESTING

Five prospective studies were conducted to determine comparability, repeatability and reproducibility of the measurement data between the CIRRUS photo and Cirrus HD-OCT Model 4000 instruments.

ANTERIOR SEGMENT STUDY

REPEATABILITY AND REPRODUCIBILITY OF CIRRUS PHOTO CENTRAL CORNEAL THICKNESS MEASUREMENTS AND COMPARISON TO CIRRUS HD-OCT

A study was conducted to evaluate the equivalence of the mean values of the Central Corneal Thickness (CCT) measurement parameter between the CIRRUS photo and Cirrus HD-OCT, Model 4000 and to determine repeatability and reproducibility of the CIRRUS photo instrument measurements of CCT.

The study inclusion criteria required adult males or females with no known corneal disease or surgery and who were able and willing to make the required study visits, give consent and follow study instructions. In addition, it was required that the subject's study eye have best corrected visual acuity of 20/40 or better and did not have: any previous surgery or laser procedures on the cornea; any corneal abnormality upon slit lamp examination or any abnormality upon examination with a CIRRUS model 4000.

The study exclusion criteria required that the subject's study eye did not have prior refractive or corneal surgery and could not present with known corneal disorders such as keratoconus, corneal leukoma, degenerative diseases, active inflammation, or infections. Subjects with any corneal abnormality upon examination with a slit lamp or a CIRRUS model 4000 were excluded as were subjects who had any known allergy to anesthetic eye drops or whose best corrected visual acuity was worse than 20/40 in the study eye. In addition, blind subjects or those who had low vision and/or severely diseased eyes or who were unable to make the required study visits, give consent or follow study instructions were excluded.

The study was divided into two phases. CCT measurements with the CIRRUS photo and Cirrus HD-OCT, Model 4000, were obtained during both phases. During both phases, three acceptable Anterior Segment Cube 512x128 scans were taken from each device.

Twenty-nine subjects were enrolled in Phase I. A single operator obtained scans from all four devices (three CIRRUS photo instruments and one Cirrus HD-OCT) to determine inter-device variability. Twenty-three subjects were enrolled in Phase II. Three operators obtained scans on each of three CIRRUS photo devices to determine inter-operator variability. One of the three operators also obtained scans from the Cirrus HD-OCT. Phase I and II enrolled different subjects; data from each phase were analyzed separately

Table 1 shows the mean difference in CCT measurements between CIRRUS photo and Cirrus HD-OCT for each phase. Overall, CCT measurements showed equivalence in the measurements between the two instruments in both phases.

Tables 2 (Phase I) and 3 (Phase II) show that the mean (of three measurements per subject), standard deviation, and 95% confidence interval of the mean CCT values are equivalent between CIRRUS photo and Cirrus HD-OCT across a large range of values covering more than 100 μm .

TABLE 1
MEAN DIFFERENCE IN CENTRAL CORNEAL THICKNESS (CCT)
BETWEEN CIRRUS PHOTO AND
CIRRUS HD-OCT OPTICAL COHERENCE TOMOGRAPHER, MODEL 4000

	Cirrus 4000 Mean¹ (SD)	CIRRUS photo Mean¹ (SD)	Difference Mean^{1,2} (SD)	95% Confidence Interval³ of Mean Difference	95% Limits of Agreement³ for Differences Between Subject means [μm]¹
Phase I	N = 28	N = 28	N = 28		
CCT [μm]	546.33 (28.37)	545.44 (28.07)	0.89 (5.04)	(-1.06, 2.85)	(-8.98, 10.77)
Phase II	N = 23	N = 23	N = 23		
CCT [μm]	539.30 (30.01)	540.51 (30.11)	-1.20 (2.28)	(-2.19, -0.22)	(-5.67, 3.27)
<p>For the inter-device phase of the study, 29 subjects were enrolled; 28 qualified for inclusion in the analysis. For the inter-operator phase of the study, 23 subjects were enrolled and qualified for inclusion in the analysis. ¹ For each of the two study devices (Cirrus HD-OCT, Model 4000 and CIRRUS photo Unit A), the average value of three measurements from one study eye were calculated (subject mean). ² Difference = CIRRUS HD-OCT, Model 4000 – CIRRUS photo. ³ 95% Confidence Interval of Mean Difference = Mean \pm 1.96 x SE. 95% Limits of Agreement = Mean \pm 1.96 x SD.</p>					

TABLE 2
PHASE I CCT COMPARISON: CIRRUS 4000 AND CIRRUS PHOTO

	Mean CCT value [μm]	95% Confidence Interval for Mean		Std. Deviation	Minimum CCT value [μm]	Maximum CCT value [μm]
		Lower Bound	Upper Bound			
Cirrus 4000	546.33	535.33	557.34	28.37	491.33	593.00
CIRRUS photo (Unit A)	545.44	534.56	556.32	28.07	477.67	595.33

TABLE 3
PHASE II CCT COMPARISON: CIRRUS 4000 AND CIRRUS PHOTO

	Mean CCT value [μm]	95% Confidence Interval for Mean		Std. Deviation	Minimum CCT value [μm]	Maximum CCT value [μm]
		Lower Bound	Upper Bound			
Cirrus 4000	539.30	526.32	552.28	30.01	494.33	603.00
CIRRUS photo (Unit A)	540.51	527.49	553.53	30.11	496.00	602.00

Analysis of Variance (ANOVA), a random effects model, was used to estimate repeatability standard deviation and reproducibility standard deviation. Repeatability and reproducibility for the CIRRUS photo are shown in Table 4.

TABLE 4
**CIRRUS PHOTO REPEATABILITY AND REPRODUCIBILITY IN
MEASURING CENTRAL CORNEAL THICKNESS (CCT)**

	Mean (N = 51)	Repeatability (microns)		Reproducibility (microns)		COV ³	
		SD	Limit ¹	SD	Limit ²	Based on Repeatability	Based on Reproducibility
CCT [μm]	542.59	4.49	12.57	5.216	14.604	0.008 (0.8%)	0.0096 (0.96%)

¹ Repeatability SD is the standard deviation under repeatability conditions. Repeatability Limit is the upper 95% limit for the difference between repeated results under repeatability conditions. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 × Repeatability SD.

² Reproducibility SD is the standard deviation under reproducibility conditions. It was estimated by the square root of the sum of repeatability variance and the variance components of operator, of device and of interaction of operator*subjects and device*subjects.
Reproducibility Limit is the upper 95% limit for the difference between repeated results under reproducibility conditions.

Reproducibility Limit = 2.8 × Reproducibility SD.

³ COV = Coefficient of Variation = SD ÷ Mean.(× 100). SD is either Repeatability SD or Reproducibility SD.

CIRRUS photo showed good repeatability and reproducibility across a large range of values.

POSTERIOR SEGMENT STUDIES

REPEATABILITY AND REPRODUCIBILITY OF CIRRUS PHOTO MEASUREMENTS OF AREA OF INCREASED ILLUMINATION UNDER THE RPE AND COMPARISON TO CIRRUS HD-OCT

A non-significant risk multiple site study was conducted to determine the repeatability and reproducibility of CIRRUS photo measurements of increased illumination areas under the retinal pigment epithelium (RPE), and closest distance to the fovea. Another objective of the study was to evaluate the comparability of CIRRUS photo to Cirrus HD-OCT.

The study inclusion criteria required adult males or females diagnosed to have dry AMD with geographic atrophy who were able and willing to make the required study visits, give consent and follow study instructions and whose geographic atrophy lesions should: not be greater than 5 mm at its widest diameter; not have area smaller than 1.25 mm² within the 5 mm circle; not be confluent with peri-papillary atrophy; and not be combined with other lesions such as choroidal neovascularization (CNV).

The exclusion criteria required that subjects did not have a history of retinal surgery, laser photocoagulation, and/or radiation therapy to the eye; evidence of other retinal diseases of the eye, including wet AMD, diabetic retinopathy, diabetic macular edema, significant vitreomacular traction, or sub-retinal scarring; or thick media opacity or inability to fixate that precluded obtaining acceptable scans.

The evaluations were performed after foveal location was reviewed and corrected, and after manual edits to the automated segmentation algorithm were entered by the operators (when necessary and consistent with the instructions provided in the labeling). Twenty one enrolled subjects with dry AMD and geographic atrophy (GA) had at least one eye that qualified for inclusion in data analysis. The mean age of the included subjects was 79.8 years with a range of 61 to 90 years.

Subjects were examined on three CIRRUS photo instruments by three operators; each operator was assigned to a specific CIRRUS photo device; one of the three operators also obtained scans using one Cirrus HD-OCT. The operators acquired three Macular Cube 200 x 200 scans and three Macular Cube 512x128 scans on each subject from each of the four devices.

After all scans had been acquired, each operator reviewed the scans to ensure that they were centered on the fovea or corrected the foveal centration if required. In addition, the operators reviewed the segmentation of the increased illumination areas under the RPE made automatically by the advanced RPE algorithm and manually edited the segmentation as needed. Each operator was responsible for reviewing and editing the scans they acquired.

Table 5 presents the agreement between CIRRUS photo and Cirrus HD-OCT based on the first acceptable scan. The difference in measurements is very close to zero for both the area of sub-RPE illumination and the closest distance to the fovea parameters, which shows a high level of agreement between the two devices.

TABLE 5
AGREEMENT BETWEEN CIRRUS HD-OCT AND CIRRUS PHOTO
MEASUREMENTS OF AREA OF SUB-RPE ILLUMINATION
AND CLOSEST DISTANCE TO THE FOVEA

Parameter	Mean (SD), 95% CI			95% Limits of Agreement (LOA)	
	CIRRUS HD-OCT	CIRRUS photo	Difference	Lower Limit 95% CI	Upper Limit 95% CI
200x200 Scan (N = 19 Subjects)					
Area of Sub-RPE Illumination (mm ²)	7.1474 (4.3979) (5.0276, 9.2671)	7.1582 (4.3342) (5.0691, 9.2472)	-0.0108 (0.3161) (-0.1632, 0.1416)	-0.6430 (-0.9070, -0.3791)	0.6215 (0.3576, 0.8854)
Closest Distance to Fovea (mm)	0.07 (0.09) (0.02, 0.11)	0.06 (0.10) (0.02, 0.11)	0.01 (0.04) (-0.01, 0.02)	-0.08 (-0.11, -0.04)	0.09 (0.05, 0.12)
512x128 Scan (N = 19 Subjects)					
Area of Sub-RPE Illumination (mm ²)	7.1368 (4.3948) (5.0186, 9.2551)	7.1682 (4.3328) (5.0799, 9.2566)	-0.0314 (0.2964) (-0.1742, 0.1115)	-0.6242 (-0.8716, -0.3767)	0.5614 (0.3140, 0.8089)
Closest Distance to Fovea (mm)	0.13 (0.25) (0.01, 0.25)	0.11 (0.25) (-0.01, 0.23)	0.02 (0.04) (-0.00, 0.03)	-0.06 (-0.09, -0.03)	0.09 (0.06, 0.12)

For each of study eye, the first scan of the corresponding scan type (200x200 or 512x128) of the device (CIRRUS HD-OCT or CIRRUS photo) taken by Operator A was used for the agreement analysis.
Difference = CIRRUS HD-OCT - CIRRUS photo.

Tables 6 and 7 present the repeatability and the reproducibility standard deviation (SD) and limits of the CIRRUS photo for the sub-RPE illumination area measurements (Table 6) and the closest distance to the fovea (Table 7) for both 200x200 and 512x128 scans. Overall, the repeatability and reproducibility SD and limits of CIRRUS photo were small.

TABLE 6
REPEATABILITY AND REPRODUCIBILITY OF CIRRUS PHOTO
MEASUREMENTS OF AREA OF SUB-RPE ILLUMINATION

Parameter	Repeatability ^a			Reproducibility ^b		
	SD (mm ²)	Limit (mm ²)	COV%	SD (mm ²)	Limit (mm ²)	COV%
200x200 Scan	0.1099	0.3078	1.52%	0.1774	0.4968	2.45%
512x128 Scan	0.1329	0.3720	1.83%	0.2442	0.6838	3.36%

a Repeatability Limit is the upper 95% limit for the difference between repeated results.

Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.

Repeatability COV% = Repeatability SD ÷ [mean] x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.

b Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments.

Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.

Reproducibility COV% = Reproducibility SD ÷ [mean] x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.

TABLE 7
REPEATABILITY AND REPRODUCIBILITY OF CIRRUS PHOTO
MEASUREMENTS OF CLOSEST DISTANCE TO THE FOVEA

Parameter	Repeatability ^a		Reproducibility ^b	
	SD (mm)	Limit (mm)	SD (mm)	Limit (mm)
200x200 Scan	0.0343	0.0961	0.0447	0.1252
512x128 Scan	0.0397	0.1113	0.0571	0.1597

- a Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.
- b Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.

REPEATABILITY AND REPRODUCIBILITY OF CIRRUS PHOTO MEASUREMENTS OF ELEVATED RPE AND COMPARISON TO CIRRUS HD-OCT

A non-significant risk single site study was conducted to determine the repeatability and reproducibility of the CIRRUS photo measurements of RPE elevation and its comparability to Cirrus HD-OCT.

The study inclusion criteria required adult males or females diagnosed to have dry AMD with macular drusen who were able and willing to make the required study visits, give consent and follow study instructions and whose drusen volume was at least 0.02 mm³ in the central 3 mm circle, determined by a screening scan acquired with Cirrus HD-OCT 6.0.

The exclusion criteria required that subjects did not have a history of retinal surgery, laser photocoagulation, and/or radiation therapy to the eye; evidence of other retinal diseases of the eye, including wet AMD, choroidal neovascularization (CNV), diabetic retinopathy, diabetic macular edema, or significant vitreomacular traction; or thick media opacity or inability to fixate that precluded obtaining acceptable scans.

Thirty one enrolled subjects with dry AMD and drusen had at least one eye that qualified for inclusion in data analysis. The mean age of the included subjects was 80.1 years with a range of 55 to 89 years.

Each subject was scanned on three CIRRUS photo devices and one Cirrus HD-OCT device. Three operators, each assigned to a specific CIRRUS photo device, performed the study scans. One of the three operators was assigned to perform the Cirrus HD-OCT study scans as well. The operators acquired three Macular Cube 200x200 scans and three Macular Cube 512x128 scans on each subject from each of the four devices.

Table 8 presents the agreement between CIRRUS photo and Cirrus HD-OCT for the area and volume of RPE elevations within the 3 and 5 mm circles as measured by the automated algorithm based on the first acceptable scan. For both scan types (200x200 and 512x128), the

mean differences (= Cirrus HD-OCT – CIRRUS photo) are all zero or very close to zero which indicates a high level of agreement between CIRRUS photo and Cirrus HD-OCT measurements.

TABLE 8
AGREEMENT BETWEEN CIRRUS HD-OCT AND CIRRUS PHOTO
MEASUREMENTS OF AREA AND VOLUME OF RPE ELEVATION

	Mean (SD), 95% CI			95% Limits of Agreement (LOA)	
	Cirrus HD-OCT	CIRRUS photo	Difference	Lower Limit 95% CI	Upper Limit 95% CI
200x200 Scan (N = 25 Subjects)					
Area of RPE Elevation					
3 mm	1.188 (0.698)	1.228 (0.717)	-0.040 (0.141)	-0.323	0.243
Circle	(0.900, 1.476)	(0.932, 1.524)	(-0.098, 0.018)	(-0.424, -0.222)	(0.142, 0.344)
5 mm	1.784 (1.052)	1.800 (1.045)	-0.016 (0.212)	-0.439	0.407
Circle	(1.350, 2.218)	(1.369, 2.231)	(-0.103, 0.071)	(-0.590, -0.288)	(0.256, 0.558)
Volume of RPE Elevation					
3 mm	0.0542 (0.0440)	0.0566 (0.0468)	-0.0024 (0.0062)	-0.0148	0.0100
Circle	(0.0360, 0.0723)	(0.0372, 0.0759)	(-0.0050, 0.0002)	(-0.0193, -0.0104)	(0.0056, 0.0145)
5 mm	0.0799 (0.0593)	0.0817 (0.0611)	-0.0018 (0.0098)	-0.0213	0.0177
Circle	(0.0554, 0.1044)	(0.0565, 0.1069)	(-0.0058, 0.0022)	(-0.0283, -0.0144)	(0.0108, 0.0247)
512x128 Scan (N = 26 Subjects)					
Area of RPE Elevation					
3 mm	1.192 (0.534)	1.196 (0.531)	-0.004 (0.173)	-0.350	0.342
Circle	(0.977, 1.408)	(0.982, 1.411)	(-0.074, 0.066)	(-0.471, -0.229)	(0.221, 0.464)
5 mm	1.785 (1.038)	1.777 (1.010)	0.008 (0.258)	-0.507	0.523
Circle	(1.365, 2.204)	(1.369, 2.185)	(-0.096, 0.112)	(-0.688, -0.327)	(0.343, 0.703)
Volume of RPE Elevation					
3 mm	0.0491 (0.0240)	0.0489 (0.0254)	0.0002 (0.0077)	-0.0153	0.0157
Circle	(0.0394, 0.0588)	(0.0386, 0.0591)	(-0.0029, 0.0034)	(-0.0207, -0.0098)	(0.0103, 0.0211)
5 mm	0.0753 (0.0519)	0.0740 (0.0500)	0.0013 (0.0134)	-0.0255	0.0282
Circle	(0.0544, 0.0963)	(0.0538, 0.0942)	(-0.0041, 0.0068)	(-0.0348, -0.0161)	(0.0188, 0.0375)

For each of study eye, the first scan of the corresponding scan type (200x200 or 512x128) of the device (Cirrus HD-OCT or CIRRUS photo) taken by Operator A was used for the agreement analysis.

Difference = Cirrus HD-OCT - CIRRUS photo.

Tables 9 and 10 present the repeatability and the reproducibility standard deviation (SD) and limits of CIRRUS photo for the area (Table 9) and volume (Table 10) of the RPE elevations for both 200 x 200 and 512 x 128 scan types within the 3 and 5 mm circles.

For CIRRUS photo, the reproducibility coefficient of variation in percentage (COV%) were similar between the 200 x 200 scan type (ranged from 8.30% to 9.18%) and the 512 x 128 scan type (8.46% to 9.07%).

TABLE 9
CIRRUS PHOTO RPE ELEVATION REPEATABILITY AND REPRODUCIBILITY
AREA OF RPE ELEVATIONS

	Repeatability ^a			Reproducibility ^b		
	SD	Limit	COV%	SD	Limit	COV%
200x200 Scan						
Area of RPE Elevation						
3 mm Circle	0.0842	0.2357	6.96%	0.1004	0.2812	8.30%
5 mm Circle	0.1165	0.3262	6.49%	0.1553	0.4348	8.66%
512x128 Scan						
Area of RPE Elevation						
3 mm Circle	0.0808	0.2262	6.72%	0.1069	0.2994	8.89%
5 mm Circle	0.1264	0.3539	7.03%	0.1521	0.4260	8.46%

- a Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.
Repeatability COV% = Repeatability SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.
- b Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.
Reproducibility COV% = Reproducibility SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.

TABLE 10
CIRRUS PHOTO RPE ELEVATION REPEATABILITY AND REPRODUCIBILITY
VOLUME OF RPE ELEVATIONS

	Repeatability ^a			Reproducibility ^b		
	SD	Limit	COV%	SD	Limit	COV%
200x200 Scan						
Volume of RPE Elevation						
3 mm Circle	0.0036	0.0101	6.49%	0.0047	0.0131	8.45%
5 mm Circle	0.0055	0.0153	6.78%	0.0074	0.0208	9.18%
512x128 Scan						
Volume of RPE Elevation						
3 mm Circle	0.0035	0.0097	7.03%	0.0045	0.0125	9.07%
5 mm Circle	0.0058	0.0163	7.81%	0.0067	0.0188	8.99%

- a Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.
Repeatability COV% = Repeatability SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.
- b Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.
Reproducibility COV% = Reproducibility SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.

REPEATABILITY AND REPRODUCIBILITY OF CIRRUS PHOTO GANGLION CELL MEASUREMENTS AND COMPARISON TO CIRRUS HD-OCT

Two studies were conducted to determine comparability of the measurements obtained from the CIRRUS photo and the Cirrus HD-OCT Model 4000 instruments, and to determine the repeatability and reproducibility of the ganglion cell analysis (GCA) parameters. One study enrolled normal eyes and one study enrolled eyes with glaucoma.

NORMAL EYES STUDY

Sixty-three normal subjects were enrolled in a study to evaluate the equivalence of the means of eight ganglion cell (GCA) measurement parameters between the CIRRUS photo and Cirrus HD-OCT Model 4000.

The study inclusion criteria required adult males or females who had no known macular disease or glaucoma with best spectacle corrected visual acuity of 20/40 or better in both eyes and who were able and willing to make the required study visits, give consent and follow study instructions in English.

The exclusion criteria required that subjects did not present with active inflammation or infections in either eye and that their best spectacle corrected visual acuity was not worse than 20/40 in either eye. Subjects who were unable to make the required study visits or to give consent or follow study instructions were excluded.

The study was divided into two phases. Thirty subjects were enrolled in Phase 1 that evaluated inter-operator variability. For each subject, three Optic Disc Cube 200x200 scans were taken on one eye, and three Macular Cube 512x128 scans were taken on the fellow eye by each of four operators using one Cirrus HD-OCT Model 4000 and one CIRRUS photo instrument. Thirty-three subjects were enrolled in Phase 2 that evaluated inter-device variability. For each subject, three Optic Disc Cube 200x200 scans were taken on one eye, and three Macular Cube 512x128 scans were taken on the fellow eye from each of the four Cirrus HD-OCT Model 4000 instruments and each of the four CIRRUS photo instruments by one operator. Subjects could not participate in both phases. The mean age of the included subjects was 43.5, with a range from 28 to 66 years.

DISEASED EYES STUDY

Seventy-seven subjects with glaucoma were enrolled in a study to evaluate the equivalence of eight GCA measurement parameters between the CIRRUS photo and Cirrus HD-OCT Model 4000.

The study inclusion criteria required adult males or females who had been diagnosed with glaucoma and who had Humphrey Field Analyzer visual field results within the past one year. Subjects were also required to be able and willing to make the required study visit(s), give consent and follow study instructions as well as to be able to maintain fixation necessary for the study scans.

Visual field results were used to classify the subjects with glaucoma into three categories using the mean deviation (MD): mild ($MD \geq -6$ dB or better); moderate ($MD < -6$ to ≥ -12 dB) and severe ($MD < -12$ dB or worse).

The exclusion criteria required that subjects did not have a history of leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis. Subjects with evidence of significant retinal diseases of the eye, including wet AMD, diabetic retinopathy, diabetic macular edema, or significant vitreomacular traction as well as subjects with thick media opacity or inability to fixate that precludes obtaining acceptable scans were excluded. In addition, subjects with refractive error outside -12.00 D to +8.00 D spherical range or > -3.00 D cylinder or who had any active infection of anterior or posterior segments were excluded.

For each subject, three Macular Cube 512x128 scans and three Macular Cube 200x200 scans were taken on each of three CIRRUS photo instruments by three operators and one Cirrus HD-OCT instrument by one of the three operators.

Sixty-eight subjects were included in the analysis of which 37 were categorized as mild glaucoma, 16 as moderate, 13 as severe, and 2 as end stage glaucoma. The mean age of the included subjects was 67.4 years, with a range from 40 to 93 years.

DATA ANALYSIS

For each of the two study devices and each measurement parameter, the mean of the available measurements was calculated for each study eye. The difference in each of the eight GCA measurement parameters between the CIRRUS photo and Cirrus HD-OCT Model 4000 were calculated for each study eye. The mean difference, the corresponding 95% confidence intervals, and 95% limits of agreement were calculated for each measurement parameter. As the inter-operator phase utilized only one device, only the results for the inter-device phase are presented in Table 11.

The mean values of the eight thickness parameters were very similar for the two devices. The results of these two studies support the incorporation of the GCA normative database established with the Cirrus HD-OCT Model 4000 instrument into the CIRRUS photo instrument with an adjustment based on regression analysis.

Additionally, analysis of variance (ANOVA) with random effect models was used to evaluate the repeatability, inter-device variability and inter-operator variability of each measurement parameter for the CIRRUS photo. The repeatability and reproducibility standard deviation (SD) and limits for the CIRRUS photo are shown in Tables 12 and 13 for the normal and diseased eyes studies, respectively. CIRRUS photo showed good repeatability and reproducibility for both normal and diseased eyes.

GCA NORMATIVE DATABASE AND LIMITS

In order to support transference of the Cirrus HD-OCT GCA Normative Database, studies were conducted with both normal and diseased eyes to demonstrate that the measurements obtained

from the CIRRUS photo instrument were comparable to the same data obtained using the Cirrus HD-OCT. The Cirrus HD-OCT GCA Normative Database was adjusted for the CIRRUS Photo (adjusted CIRRUS photo Normative Database) using regression analysis based on the data from these studies. Then, the CIRRUS photo GCA normative limits were established based on the adjusted CIRRUS photo Normative Database.

The Cirrus GCA normative database [for the Cirrus HD-OCT] was developed utilizing 282 subjects aged 19-84. Gender distribution was 133 males, and 149 females. Ethnicity breakdown was as follows: 43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 6% mixed ethnicity.

Results revealed that the mean difference in the average ganglion cell plus inner plexiform layer (GCL + IPL) thickness between any two race groups is within 4.3 μm . Subjects of European descent have thinner GCL + IPL thickness on average, while subjects of Hispanic and Chinese descent have thicker ganglion cell plus inner plexiform layer thickness ($p < 0.001$).

Note that the GCA normative database is adjusted only by age, not by ethnicity or any other parameter. The normative limits provided for comparisons of individual data to the normative database do not take into account differences that may be present due to ethnicity, axial length, refraction, or signal strength. Regression analysis showed that signal strength and age were the two continuous parameters with the greatest effect on the GCA parameters. All other effects were small. Based on R^2 values, age explains only 12% of the variability in some parameters, while signal strength explains no more than 4%. Refractive error and axial length explain less than 2% of variability. For those reasons, only age was used when applying normative limits to Ganglion Cell Analysis parameters.

The regression model analyses were used to estimate the normative limit of each of the Cirrus photo GCA parameters adjusted by age.

TABLE 11
AGREEMENT BETWEEN CIRRUS HD-OCT AND CIRRUS PHOTO
FOR GCA PARAMETERS
(BASED ON WITHIN-EYE AVERAGE)

	Cirrus HD-OCT Mean (SD) (95% CI)	CIRRUS photo Mean (SD) (95% CI)	Difference Mean (SD)	95% Confidence Interval of Mean Difference	95% Limit of Agreement for Difference Between Subject Means
Normal Eyes	N = 33	N = 33	N = 33		
Average Thickness (μm)	82.6 (6.1) (80.4, 84.7)	82.9 (5.9) (80.8, 85.0)	-0.3 (0.4)	(-0.5, -0.2)	(-1.1, 0.4)
Minimum Thickness (μm)	80.8 (6.3) (78.5, 83.0)	80.5 (6.5) (78.3, 82.8)	0.2 (0.9)	(-0.1, 0.5)	(-1.6, 2.1)
Temporal-Superior Thickness (μm)	81.5 (6.7) (79.2, 83.9)	81.8 (6.6) (79.5, 84.1)	-0.3 (0.7)	(-0.5, -0.0)	(-1.6, 1.1)
Superior Thickness (μm)	83.1 (5.8) (81.1, 85.2)	83.5 (5.7) (81.5, 85.5)	-0.4 (0.5)	(-0.5, -0.2)	(-1.3, 0.6)
Nasal-Superior Thickness (μm)	85.2 (5.7) (83.2, 87.2)	85.4 (5.9) (83.3, 87.5)	-0.2 (0.8)	(-0.5, 0.1)	(-1.8, 1.4)
Nasal-Inferior Thickness (μm)	83.1 (6.2) (80.9, 85.3)	83.3 (6.1) (81.2, 85.5)	-0.3 (0.6)	(-0.5, -0.1)	(-1.4, 0.8)
Inferior Thickness (μm)	80.2 (6.2) (78.0, 82.4)	80.7 (6.0) (78.6, 82.8)	-0.5 (0.7)	(-0.7, -0.3)	(-1.8, 0.8)
Temporal-Inferior Thickness (μm)	82.4 (7.0) (79.9, 84.9)	82.8 (6.8) (80.4, 85.2)	-0.4 (0.6)	(-0.6, -0.2)	(-1.5, 0.7)
Diseased Eyes	N = 68	N = 68	N = 68		
Average Thickness (μm)	65.4 (8.8) (63.3, 67.5)	65.7 (9.0) (63.6, 67.9)	-0.3 (0.6)	(-0.5, -0.2)	(-1.5, 0.8)
Minimum Thickness (μm)	59.5 (11.2) (56.8, 62.2)	59.4 (11.6) (56.6, 62.2)	0.1 (1.0)	(-0.2, 0.3)	(-1.9, 2.0)
Temporal-Superior Thickness (μm)	64.8 (9.6) (62.5, 67.2)	65.1 (10.0) (62.7, 67.5)	-0.2 (0.9)	(-0.5, -0.0)	(-2.1, 1.6)
Superior Thickness (μm)	66.5 (9.8) (64.1, 68.9)	66.8 (10.2) (64.3, 69.2)	-0.3 (1.0)	(-0.5, -0.0)	(-2.3, 1.7)
Nasal-Superior Thickness (μm)	68.9 (10.2) (66.5, 71.4)	69.4 (10.4) (66.9, 71.9)	-0.5 (0.7)	(-0.7, -0.3)	(-1.9, 1.0)
Nasal-Inferior Thickness (μm)	66.2 (10.2) (63.7, 68.6)	66.6 (10.4) (64.1, 69.1)	-0.4 (1.1)	(-0.7, -0.2)	(-2.5, 1.7)
Inferior Thickness (μm)	63.0 (9.3) (60.8, 65.3)	63.5 (9.8) (61.1, 65.8)	-0.4 (1.1)	(-0.7, -0.2)	(-2.6, 1.7)
Temporal-Inferior Thickness (μm)	63.0 (10.0) (60.6, 65.4)	63.2 (10.4) (60.7, 65.7)	-0.2 (0.9)	(-0.5, -0.0)	(-2.1, 1.6)

For each of the two study devices, the average of measurements from different units and/or operators were calculated for each eye was treated as the measurement for the corresponding eye.

Difference = Cirrus HD-OCT - CIRRUS photo.

TABLE 12
CIRRUS PHOTO REPEATABILITY AND REPRODUCIBILITY OF GCA PARAMETERS
(NORMAL EYES)

	Repeatability ^a			Reproducibility ^b		
	SD	Limit	COV%	SD	Limit	COV%
Average GCL+IPL Thickness (μm)	0.6103	1.7088	0.73%	0.8113	2.2717	0.97%
Minimum GCL+IPL Thickness (μm)	2.5420	7.1177	3.13%	2.9236	8.1860	3.59%
Temporal-Superior GCL+IPL Thickness (μm)	0.7773	2.1765	0.94%	1.0566	2.9584	1.28%
Superior GCL+IPL Thickness (μm)	1.1381	3.1866	1.35%	1.3168	3.6870	1.57%
Nasal-Superior GCL+IPL Thickness (μm)	1.5900	4.4519	1.86%	1.6579	4.6422	1.94%
Nasal-Inferior GCL+IPL Thickness (μm)	1.1854	3.3191	1.42%	1.4391	4.0296	1.72%
Inferior GCL+IPL Thickness (μm)	1.1453	3.2068	1.41%	1.4621	4.0939	1.80%
Temporal-Inferior GCL+IPL Thickness (μm)	0.7444	2.0843	0.89%	1.0221	2.8618	1.22%

- a Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.
Repeatability COV% = Repeatability SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.
- b Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.
Reproducibility COV% = Reproducibility SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.

TABLE 13
CIRRUS PHOTO REPEATABILITY AND REPRODUCIBILITY OF GCA PARAMETERS
(DISEASED EYES)

	Repeatability ^a			Reproducibility ^b		
	SD	Limit	COV%	SD	Limit	COV%
Average GCL+IPL Thickness (μm)	0.5982	1.6750	0.91%	0.6413	1.7955	0.98%
Minimum GCL+IPL Thickness (μm)	1.8262	5.1133	3.07%	1.8774	5.2566	3.16%
Temporal-Superior GCL+IPL Thickness (μm)	0.9785	2.7399	1.50%	1.0804	3.0251	1.66%
Superior GCL+IPL Thickness (μm)	1.1455	3.2073	1.72%	1.1568	3.2391	1.73%
Nasal-Superior GCL+IPL Thickness (μm)	1.0455	2.9273	1.51%	1.0585	2.9638	1.52%
Nasal-Inferior GCL+IPL Thickness (μm)	1.2301	3.4442	1.85%	1.3019	3.6454	1.96%
Inferior GCL+IPL Thickness (μm)	1.2314	3.4479	1.94%	1.3262	3.7133	2.09%
Temporal-Inferior GCL+IPL Thickness (μm)	0.9129	2.5560	1.44%	1.0476	2.9333	1.66%

- a Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD. Repeatability COV% = Repeatability SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.
- b Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725-1 and ISO 5725-6, Reproducibility Limit = 2.8 x Reproducibility SD.
Reproducibility COV% = Reproducibility SD ÷ |mean| x 100%. The mean was the estimated general mean in the random ANOVA model for the R&R calculation.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on the CIRRUS photo to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

March 19, 2014

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

Ms. Mandy Ambrecht
Staff, Regulatory Affairs Specialist
Carl Zeiss Meditec AG
5160 Hacienda Drive
Dublin, CA 94568

Re: K133217

Trade/Device Name: CIRRUS photo Models 600 and 800
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, HKI
Dated: February 11, 2014
Received: February 14, 2014

Dear Ms. Ambrecht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRII does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K133217

Device Name: CIRRUS photo Models 600 and 800

Indications For Use:

The CIRRUS photo is a non-contact, high resolution tomographic and biomicroscopic imaging device that incorporates a digital camera which is suitable for photographing, displaying and storing the data of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions.

These photographs support the diagnosis and subsequent observation of eye diseases which can be visually monitored and photographically documented. The CIRRUS photo is indicated for in vivo viewing, axial cross sectional, and three-dimensional imaging and measurement of posterior ocular structures, including retina, retinal nerve fiber layer, macula and optic disc as well as imaging of anterior ocular structures and measurement of central corneal thickness.

It also includes a Retinal Nerve Fiber Layer (RNFL), Optic Nerve Head (ONH), and Macular Normative Database which are quantitative tools for the comparison of retinal nerve fiber layer, optic nerve head, and the macula in the human retina to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

Prescription Use X
(part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Daniel P. Fedorko -S

2014.03.18 16:11:26 -04'00'

(Division Sign-Off)

Division of Ophthalmic and Ear, Nose, and
Throat Devices

510(k) Number: K133217